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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,760	03/18/2004	Renato Angelo Marchesini	2503-1083	4670

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EXAMINER
ABRAHAM, SALIEU M

ART UNIT	PAPER NUMBER
3768	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/802,760	MARCHESINI ET AL.	
	Examiner	Art Unit	
	SALIEU M. ABRAHAM	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *12,13,20 and 21* is/are allowed.

6)☒ Claim(s) *8-11,14-18 and 23-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 September 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments/Remarks

1. Examiner acknowledges applicant's cancellation of claims 1-7 and addition of new claims 8-24. Claims 8- 24 are pending in the application.

2. Examiner further acknowledges applicant's corrections to address drawing deficiencies, claim objections and rejections under 35 U.S.C. 112 2nd paragraph presented in the prior office action.

3. As a result of the items (1-2) supra, all claim objections and rejections from the prior office action are hereby withdrawn. The instant Office Action is made non-final.

Claim Objections

4. Claims 9 and 10 are objected to because of the following informalities: the claims improperly reference a cancelled claim (claim 1). Appropriate correction is required.

35 USC § 112, sixth paragaraph

5. The following is a quotation of the sixth paragraph of 35 U.S.C. 112:

> An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.
>
> (Amended July 24, 1965, Public Law 89-83, sec. 9, 79 Stat. 261; Nov. 14, 1975, Public Law 94-131, sec. 7, 89 Stat. 691.)

a. A claim limitation will invoke 35 U.S.C. 112, sixth paragraph if it passes the following three-pronged test:

i. The claim limitations **must use** the phrase "means for" or "step for",

ii. The phrase "means for" or "step for" **must be modified** by functional language, and

iii. The phrase "means for" or "step for" **must not be modified** by sufficient structure, material or acts for achieving the specified function.

6. Claim 1 invokes 35 U.S.C. 112, sixth paragraph, as it meets all the requirements of the three-pronged test above. Therefore, the following claim limitations are being treated as invoking 35 U.S.C. 112, sixth paragraph in this action for art rejection purposes:

In Reference to Claim 1:

means for acquiring images of a pigmented skin lesion with lighting at different wavelengths.

Have been interpreted as covering the following equivalents as described and when viewed in light of the specification:

the specified means could refer to the following pigmented skin lesion multispectral light image acquisition equivalents: a fiberoptic **probe** coupled with a multispectral **video device** such as a ***camera*** capable of producing monochromatic or color images, and a fiberoptic or equivalently optically coupled white light illumination **device** (i.e. a halogen or xenon lamp), and **spectral filters** for extracting light in specific spectral ranges and blocking out light in other spectral ranges such as blue and ultraviolet (UV) light (see fig.4, page 4, lines 22-25, page 5, lines 9-13 and page 7, lines 8-15).

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 8, 10-11, 15, 19 and 22 - 24 are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat. No. 6,208,749 to Gutowicz-Krusin (Gutowicz-Krusin).

In Reference to Claims 8 and 15

Gutowicz-Krusin teaches an apparatus for the characterization of pigmented skin lesions (abstract), comprising:

means for acquiring images of a pigmented skin lesion with lighting at different wavelengths (figs. 1a and 1b) to include fiberoptic probe (5), video camera (6), white light illumination device (3) and spectral filters (4); computer (12) having storage (12b) , display (19) and interface (12a) to the lesion image acquisition means, the computer configured to parameterize individual images and obtain a resulting data set (fig. 1a, and 3b, 60-68), col. 12, lines 37-43), process and provide a classification threshold value for the data (col. 12, lines 43-55), perform neural net processing on resulting image data (col. 12, lines 47-49), make comparisons between threshold value and neural network output and vary the weighting of the parameters applied to the neutral net based upon the comparison results (col. 12, lines 43-55); computer operations may more specifically encompass obtaining first and second image data sets based on

imager acquired skin lesion physical characteristics where the first data set is presented to the neural net and the second is used to generate a classification threshold value from a set of known results (cols. 3, lines 65-67, 4, lines 1-25 and 12, lines 25-55), and normalization of descriptor values by means of a normalization function that encompasses minimum and maximum values of descriptors for all acquired images (fig. 3a, steps 3 and 4 and col. 11, lines 43-50) .

In Reference to Claims 10 and 11

Gutowicz-Krusin further teaches wherein the computer is further configured to store descriptor values for all images in an archive (claim 68), normalize descriptor values by means of a normalization function that encompasses minimum and maximum values of descriptors for all acquired images (fig. 3a and col. 11, lines 43-50), obtain for each lesion dimensions, variegation, reflectance in the visible and infra-red (IR) light zones(col. 4, lines 5-16 and 48-54), presence of dark patches (col. 17, lines 5-12) and dark patch to rest of the lesion ratio (col. 11, lines 40-50).

In Reference to Claim 19

Gutowicz-Krusin further teaches wherein the physical characteristics include skin lesion dimension, variegation, reflectance in visible and IR light (col. 4, lines 5-16 and 48-54), presence of dark patches in lesion (col. 17, lines 5-12), and ratio of dark patch and remaining areas of lesion (col. 11, lines 40-50).

In Reference to Claims 22-24

Gutowicz-Krusin further teaches wherein the computer is further configured to derive from parameters a value indicating an influence of a variation in one of the descriptors on a classification of a lesion (col. 17, lines 5-42) and acquire a plurality of images from an imager at different wavelengths (see figs. 1a and 2, and cols. 7, lines 60-68 and 8, lines 1-12), and wherein the imager uses light in the 480 -1000 nm wavelength range (fig. 1b and col. 4, lines 48-54).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 9, 14, and 16 are rejected under 35 U.S.C. under 35 U.S.C. 103(a) as being unpatentable over Gutowicz-Krusin in view of Ganster et al., "Automated Melanoma Recognition", IEEE Transactions on Medical Imaging, March 2001, Vol. 20, No. 3, pages 233-239. (hereinafter Ganster)

In Reference to Claims 9 and 14

Gutowicz-Krusin further has been shown to teach all claim 1 limitations. Gutowicz-Krusin further teaches an apparatus for the characterization of pigmented skin

lesions wherein the computer is further configured to process images acquired at different wavelengths to extract descriptors of the lesion (col. 3, lines 10-42). However, Gutowicz-Krusin is silent with respect to descriptor reduction resulting in fewer variable selection that would allow retention of a large percentage (>= 85%) of the (total data) variance for reliable lesion pathological state classification (see instant application sections 0014-0015).

Ganster in the same field of endeavor (abstract) discloses reducing descriptors (features) in order to only include the most significant features that allow reliable lesion classification while minimizing (the number of) variables (for neural network input; pp. 233-234, Feature Selection and Classification).

Therefore, it would have been obvious to one ordinary skill in the art to have modified the invention of Gutowicz-Krusin by incorporating a descriptor reduction means as described by Ganster in order to use the most significant and fewest possible descriptors that would still allow for reliable lesion classification as taught by Ganster (p. 234, para. 1-3).

In Reference to Claim 16

Gutowicz-Krusin further has been shown to teach all claim 15 limitations. Gutowicz-Krusin further teaches applying statistical analysis to variables within a first data set for classification to obtain a sub-set of said variables (col. 17, lines 5-41). However, as described before Gutowicz-Krusin is silent with regard to descriptor and variable reduction whereby over 85% variance is retained by the variables, but this

basis is provided by Ganster as discussed supra (see rejection for claims 9 and 14).

11. Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gutowicz-Krusin.

In Reference to Claim 17

Gutowicz-Krusin has been shown to teach all claim 15 limitations. While Gutowicz-Krusin does not use the same formula for normalization of descriptor values as applicant, normalization of descriptor values by means of a normalization function that encompasses minimum and maximum values of descriptors for all acquired images is disclosed by Gutowicz-Krusin (fig. 3a and col. 11, lines 43-50). It would be obvious to one of ordinary skill in the art that the two formulas (e.g. applicant's and Gutowicz-Krusin 's) are functionally equivalent as they both normalize descriptor minimum and maximum values for use in skin cancer (i.e. melanoma) classification.

In Reference to Claim 18

Gutowicz-Krusin has been shown to teach all claim 15 limitations. Gutowicz-Krusin further teaches the imager (figs. 1a and 1c) in addition to a target imaging video camera (fig. 1a, 6) further comprises a target illuminator (5), first monochrome sensor (6), second color sensor (fig. 1c, 20), the monochrome sensor responsive to light in the visible (480 nm) to infrared (1000 nm) range. However, while the apparatus of Gutowicz-Krusin doesn't make use of a multi-wavelength producing rotating mirror, it does include embodiments that utilize mirrors(lenses) and filter wheels to effect the generation of varying or multiple wavelengths. It would be obvious to one ordinary skill

that the two are functional equivalents (achieve the same ends <produce different wavelengths> for the same application/solving same problem <classifying skin lesion pathology>) or obvious variants of one another.

Allowable Subject Matter

12. Claims 12, 13, 20 and 21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

13. The following is a statement of reasons for the indication of allowable subject matter: claims 12-13 and 20-21 are allowed because the prior art neither anticipates nor renders obvious the renders the limitations of base claims 12 and 20 with respect to the mode of generating descriptor values for neural network training in combination with the other claim elements, to include graphically displaying network output values using a curve, and descriptor and threshold values via a point and line respectively. Further, with respect to claims 13 and 21, the derivation of a value indicative of the influence of a variation in a descriptor on lesion classification was not found or reasonably suggested in the prior art as well.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Elbaum, Kenet and Skladnev have been included because they respectively encompass color and infrared imaging apparatus and methods which find utility in measurements of color or pigmentation from different parts of the body similar

to those described by the applicant for the proposed invention.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Salieu M. Abraham whose telephone number is (571) 270-1990. The examiner can normally be reached on Monday through Thursday 10:30 am - 7:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SA

/Long V Le/
Supervisory Patent Examiner, Art Unit 3768